

Special 510(k): Device Modification
Siemens MultiView WorkStation Infinity Telemetry System

510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: November 8, 2000

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens MultiView WorkStation Infinity Telemetry System

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Cardiac monitor	74DRT	II	21 CFR 870.2300
Pulse rate monitor	74BWS	II	21 CFR 870.2300
Pulse oximeter	74DQA	II	21 CFR 870.2700
Radiofrequency physiological signal transmitter and receiver	74DRG	II	21 CFR 870.2910
Arrhythmia detector & Alarm	74DSI	III	21 CFR 870.1025
Medical Cathode-Ray Tube Display	74DXJ	II	21 CFR 870.2450
ST Segment Monitor with Alarm	74MLD	III	21 CFR 870.1025

Legally Marketed Device Identification:

Siemens MultiView WorkStation Infinity Telemetry System

Description of Modifications:

The MultiView WorkStation Infinity Telemetry System, 510(k) K972714, has been modified with an additional frequency range. The INFINITY MultiView Telemetry System integrates patient monitoring by the simplex VHF/UHF band ABT/MicroO2 ambulatory telemetry transmitter with a MultiView WorkStation. The original design [510(k) K972714] included transmitter frequency ranges 174 – 216 MHz (VHF), 400 – 460 MHz, and 512 – 566 MHz (UHF). The additional frequency range of 608 - 614 MHz (UHF) is a technology improvement that expands the number of transmitter channels possible.

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In addition, the modified MultiView WorkStation (MVWS) Infinity Telemetry System software (VF0) enables the Supra Ventricular Tachycardia (SVT) call. SVT occurs when N (SVT count) or more consecutive normal beats are detected with a beat-to-beat rate greater than or equal to the SVT rate. This arrhythmia call is an extension of the existing software design, implementation of which introduced no new design considerations. The original design that integrated the ECG algorithms into the MVWS Infinity Telemetry System treats all algorithm output identically. Parameter and arrhythmia calls are produced by the algorithms, analyzed for alarms, and forwarded to other subsystems in the product. The previous software release, VE0, was a modification that included arrhythmia calls for Sinus Tachycardia, Sinus Bradycardia and Pause [510(k) K983980].

Tests performed on the modifications raise no new issues of safety and efficacy.

Intended Use: (Same as K972714)

Biocompatibility: Not applicable

Sterilization: Not applicable

Standards and Guidances: (Same as K972714)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 9 2000

Ms. Penelope Greco
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K003179
Trade Name: Siemens Multiview Workstation Infinity Telemetry
System
Regulatory Class: III (three)
Product Code: DSI
Dated: October 10, 2000
Received: October 13, 2000

Dear Ms. Greco:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

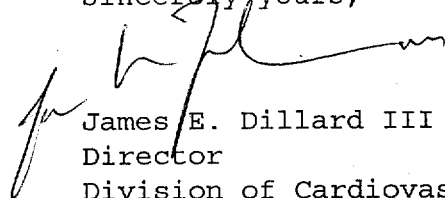
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for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read "James E. Dillard III", is written over the typed name and title.

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Siemens MultiView WorkStation INFINITY Telemetry System

Indications for Use:

Use of the MultiView WorkStation INFINITY Telemetry System is indicated for adult and pediatric patient populations in an environment where patient care is provided by Healthcare Professionals (Physicians, Nurses, Technicians) when the professional determines that a device is required to measure and produce visual and audible alarms for any one or more of the following parameters:

- Heart rate
- ECG Arrhythmia Analysis
- Arterial oxygen saturation
- Pulse rate
- ST segment analysis

MRI Compatibility Statement:

The MultiView WorkStation Infinity Telemetry System is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)


Division of Cardiovascular & Respiratory Devices
510(k) Number 1200 3179